

### **REMARKS/ARGUMENTS**

In view of the foregoing amendments and following remarks, favorable reconsideration of the pending claims.

#### ***Status of the Claims***

Claims 1, 3-5, 7-12, 16-19, 21 and 22 are pending. Claims 2, 6, 13-15, and 20 have been cancelled.

Claim 1 has been amended to clarify that the particles of dehydrated lactic acid bacteria are coated with at least one vegetable fat that is solid at ambient temperature, and that the coated particles have an average size of less than 200  $\mu\text{m}$ . The references to granules have been removed from the claims.

Claims 3, 11, 12, 1-18, 21, and 22 have been amended to be consistent with the amendments to Claim 1.

#### ***Rejections under 35 U.S.C. § 112***

Claims 1, 3-5, 7-12, 16-19, and 21-22 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. See Examiner's comments on page 3 of the Office Action.

Claim 1 has been rejected as being indefinite because the Examiner alleges that it is not clear as to whether a granulation process is done after coating the lyophilized bacteria or the coated bacteria are simply called granules. Claim 1 has been amended to clarify that the term "particles" refers to the bacterial prior to coating and the term "coated particles" refers to the bacteria following coating. Moreover, the specification is unambiguous regarding the notion of "particles of dehydrated bacteria". That is, where the specification mentions these particles, it means the dehydrated bacteria before the step of granulation, i.e. without any coating. In view of this clarifying amendment, Applicant submits that this rejection has been overcome.

Claim 1 has also been rejected for the acronym " $M_p$ ". Claim 1 has been amended to clarify that the term " $M_p$ " refers to the melting point.

Claims 11 and 12 have been rejected as being indefinite because it is allegedly not clear whether the particle size of the coated particles or granules are being recited or the bacteria after

lyophilization measure 80-150 microns before coating them. Claim 11 has been amended to clarify that the particles of bacteria (following lyophilization) have a size that is 80-150 microns. Accordingly, it can be seen that Claim 11 refers to the size of the particles of dehydrated bacteria prior to being coated.

Applicant submits that the rejection of Claim 12 has been overcome by the amendments to Claim 1.

Claim 19 has been rejected as being indefinite. Applicant respectfully submits that the concentration of bacteria per gram of the product may be evaluated by very usual methods for the person skilled in the art; for example, the bacteria concentration in the particles may be determined taking into account the bacteria concentration in the culture medium just before a dehydration step. As such, Applicant submits that Claim 19 is not indefinite.

In view of the foregoing amendments and remarks, it is respectfully submitted that the rejections under 35 U.S.C. § 112, second paragraph, have been overcome.

#### ***Prior Art Rejections***

Claims 1, 3-5, 7-12, 16-19, and 21-22 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Shin et al. (US 6,447,823) in view of Rutherford et al. (US 5,292,657). Applicant respectfully traverses the rejections.

Before discussing the rejections in detail, it is important to briefly note that the technical problem to which present invention is directed is the preparation of a liquid aqueous food product containing viable probiotic microorganisms encapsulated in granules that are not perceptible in the mouth when drinking said liquid food product; more specifically, the purpose is thus to maintain said microorganisms viable in a low pH (4.5 or less) and highly aqueous (water content of at least 90%) environment.

This technical problem has been solved by the encapsulation of dried microorganisms with vegetable fats that are solid at ambient temperature in such a way that the granules of encapsulated microorganisms have an average size of less than 200  $\mu\text{m}$ . The small granules size (i.e., coated particle size) is crucial for purposes of distribution/dispersion stability in liquid food products and taste effect (to avoid perception of the granules when consuming the liquid food product).

***1. The combination of R1 and R2 does not disclose or suggest the claimed invention***

Shin et al. (US 6,447,823, **R1**) describes a liquid yogurt containing lactic acid bacteria encapsulated using a mixture of hardened oil and of starch; the size of the capsules thus obtained is very large: 1 to 3 mm (col. 3, lines 66-67 and col. 8, lines 16-17).

The purpose of **R1** is to prepare a yogurt in which the capsules of lactic acid bacteria are uniformly distributed.

The solution proposed by **R1** to this technical problem is to prepare liquid yogurt and lactic acid capsules having substantially the same gravity.

Another purpose of **R1** is to protect the lactic acid bacteria from the gastric acid within the stomach so that the lactic acid bacteria can maximally survive until it reaches the intestine.

**R1** overcomes this problem by first mixing the lactic acid bacteria with hardened oil and starch (col. 4, lines 49, lines 53 and lines 62; col. 5, lines 2, lines 40 and lines 61, col. 6, line 1, col. 8, line 46 and line 51), during a second step, hardened oil and starch are spread on to capsules to form a protective coating layer.

In the Office Action, the Examiner stresses that **R1** was silent regarding lack of starch in the granules and regarding the use of granules size of less than 200  $\mu\text{m}$ . Accordingly, these recitations are clearly missing from the teachings of **R1**.

It should also be noted that **R1** relates to liquid yogurts, which are textured food products, having a water content by weight below 90%<sup>1</sup>; more particularly, **R1** is silent regarding beverages having a water content by weight of at least 90%, as recited in the instant claims. As such, **R1** also fails this teaching, and is not particularly relevant to the problem and solution addressed by the claimed invention.

Furthermore, the lactic acid bacteria capsules of **R1** are different from the lactic acid bacteria granules according to the present invention as capsules of **R1** are such that bacteria are mixed with hardened oil and starch, whereas dehydrated bacteria in the granules of the present invention are not mixed with any fat.

---

<sup>1</sup> For example, Actimel®, the drinkable yogurt sold by Danone, contains less than 88% of water by weight.

Rutherford et al. (US 5,292,657, **R2**) fails to cure the deficiencies of **R2**. As previously detailed, **R2** describes the preparation of freeze-dried microorganisms entrapped in a fatty acid matrix capable of maintaining bacterial activity in acidic environment; the entrapped freeze-dried microorganisms are obtained with very specific equipment.

**R2** uses a very particular process (different from the method used for preparing granules according to the present invention) leading to the granules in which microorganisms are mixed and entrapped into the fatty acid matrix whereas particles of microorganisms of the present invention are coated with vegetable fat solid at ambient temperature.

**R2** does not describe or provide any guidance as to how to formulate the capsules in liquid food products. In particular, the microspheres of **R2** may only be mixed in a dry feed product. Accordingly, one of ordinary skill in the art would not look to the teachings of **R2**, and would certainly not look to its teachings in combination with **R1**, which as noted above is directed to a yogurt food product.

Accordingly, it can be seen that the combination of **R1** and **R2** fails to disclose or suggest any one of:

- (i) an aqueous beverage containing at least 90% of water; and
- (ii) coated particles comprising a core composed of dehydrated lactic acid bacteria and a coating layer of vegetable fat.

As such, the combination of **R1** and **R2** fails to disclose each and every element of Claim 1 and therefore the Examiner has failed to establish a prima facie case of obviousness. Withdrawal of this rejection is respectfully requested.

**2. One of Ordinary Skill in the Art would not combine R1 and R2 as contemplated by the Examiner**

The preparation of a dispersion of microspheres in a liquid food product and the taste of these microspheres are not problems that need to be addressed or is even a concern in **R2**. As such, the teachings of **R2** are clearly not relevant to the teachings of **R1**, let alone the claimed invention. Accordingly, one of skill in the art would not look to the teachings of **R2** as contemplated by the Examiner.

More particularly, the person skilled in the art would find no incentive to combine the teaching of **R2** and **R1** to address the problem addressed by the present invention:

- none of these references are relevant to address the problem of preparing an aqueous beverage with imperceptible granules of probiotics: in sharp contrast, the liquid yogurts of **R1** have a semi-solid texture with a sick consistency, granules are less perceptible in liquid yogurt than in aqueous liquid food product; and **R2** refers only to dry products;

- the person skilled in the art who tries to prepare an aqueous beverage would not have considered the teaching of **R2** which concerns dry feed product;

- the process for preparing granules of **R2** is very specific, the obtained granules do not necessarily have a gravity compatible with the gravity of the liquid yogurt of **R1**. As noted above, **R1** teaches preparing a liquid yogurt having lactic acid capsules that have substantially the same gravity as the yogurt medium to ensure uniform mixing. Given this significant requirement in the teachings of **R1**, it can be seen that **R1** and **R2** cannot be predictably combined or combined with an expectation of success.

- further based on the requirement of a specific gravity in **R1**, one of ordinary skill in the art would have had to overcome a technical prejudice to combine these two documents;

- as they are essentially composed of fat and they do not contain any starch, the granules of **R2** are very lipophilic (more than the granules of **R1**); as a consequence, a person skilled in the art would have been deterred from using such granules in water containing food product such as liquid yogurt of **R1**.

As noted above, even if one tries to combine the liquid yogurt of **R1** with the granules of **R2**, the resulting product does not disclose or suggest each and every element of Claim 1. In particular, the combination of **R1** and **R2** fails to disclose or suggest any one of:

- (i) an aqueous beverage containing at least 90% of water; and
- (ii) coated particles comprising a core composed of dehydrated lactic acid bacteria and a coating layer of vegetable fat.

As previously explained, even by combining the teachings of **R1** and **R2**, a person skilled in the art would not have prepared a liquid food product containing granules of probiotic microorganisms that are not perceptible in the mouth.

**3. *The Claims invention provides surprising and unexpected benefits***

Compared to the prior art, the combination of technical features of the food product according to claim 1 leads surprisingly to:

- a very good viability of the microorganisms as shown in the experimental examples of the present Application;
- a very good dispersion and physical stability of the lipophilic granules in the essentially aqueous food product; and
- a very good organoleptic quality of the liquid food product: granules are not perceptible in the mouth when mixed with a liquid food product (feeling of grains of sand on the palate).

Given the above, the liquid food product of claim 1 and any claims dependent thereon is not obvious in view of the teaching of **R1** and **R2**, or any combination of **R1** and **R2**. For these additional reasons, Applicant submits that the rejections based on the combination of **R1** and **R2** should be withdrawn.

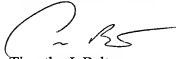
In view of the foregoing amendments and remarks it is respectfully submitted that the rejections under 35 U.S.C. § 103(a) and 112 have been overcome and that the pending claims are in condition for immediate allowance.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any required fee

Appl. No.: 10/596,789  
Amdt. dated 02/17/2011  
Reply to Office Action of 08/17/2010

(including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,



Timothy J. Balts  
Registration No. 51,429

**Customer No. 00826**  
**ALSTON & BIRD LLP**  
Bank of America Plaza  
101 South Tryon Street, Suite 4000  
Charlotte, NC 28280-4000  
Tel Charlotte Office (704) 444-1000  
Fax Charlotte Office (704) 444-1111

ELECTRONICALLY FILED USING THE EFS-WEB ELECTRONIC FILING SYSTEM OF THE UNITED STATES PATENT & TRADEMARK OFFICE ON **FEBRUARY 17, 2011.**